



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Via Federal Express

JUN 28 2001

WARNING LETTER

Mr. Tom Goldman
President
Bayshore Community Hospital
727 North Beers Street
Holmdel, New Jersey 07733

Dear Mr. Goldman:

During the period of April 23-24, 2001, Ms. Jean M. Kelahan, an investigator with the Food and Drug Administration (FDA), New Jersey District Office, inspected the institutional review board (IRB) at your facility. The purpose of this inspection was to determine whether your IRB's activities and procedures relating to investigational studies of FDA-regulated products complied with applicable FDA regulations.

We have completed our review of the report submitted by the district office which described and documented violations of the requirements of Title 21, Code of Federal Regulations (21 CFR), Part 56 - Institutional Review Boards, and Part 812 - Investigational Device Exemptions. These violations were listed on the Form FDA-483 "Inspectional Observations" that was presented to L. Scott Larsen, M.D., Chairman of the Bayshore Community Hospital IRB and discussed with Dr. Larsen and [REDACTED] the IRB's [REDACTED] at the conclusion of the inspection. The description of violations that follows is not intended to be an all-inclusive list of all of the IRB's deficiencies.

The written procedures do not adequately meet the regulatory requirements of 21 CFR 56.108(b) and 21 CFR 56.115(a)(6). The IRB's written procedures entitled, "The Bayshore Community Hospital I.R.B. Manual," lack the following procedures:

- for determining which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;
- for ensuring prompt reporting to the IRB, appropriate institutional officials and the FDA of instances of serious or continuing noncompliance of investigators with the regulations or the requirements of the IRB;
- for ensuring prompt reporting to the FDA of unanticipated problems including risks to human subjects;
- for determining "Significant Risk" (SR) versus "Non-significant Risk" (NSR) for medical device investigations.

In addition, the written procedures do not contain a description of the qualifications for IRB membership or a statement as to the length of time the IRB records are to be maintained.

Futhermore, review of IRB meeting minutes and other records related to the review of the "Manual," or by-laws as revised during 1998-2000, disclosed that there was no documentation that the revisions covering the following procedures were approved by the full IRB committee, the IRB Chairman, or any other institutional official.

The IRB failed to conduct review of research in accordance with the procedures described in their written procedures or as required by 21 CFR 56.108(c). Neither a majority of members nor a quorum, as defined in the procedures, were present when review of research was conducted at convened meetings of the IRB.

- Minutes of the IRB meeting of June 8, 1999, indicate that only six of nineteen members listed on the membership roster in effect at that time attended the meeting. The meeting lacked a quorum (two-thirds of its members as defined in the IRB procedures). The meeting also lacked a simple majority of members as required by 21 CFR 56.108(c). Further review of the minutes disclosed that initial review of the [REDACTED] was approved by the IRB at that meeting.
- Minutes of the meeting of September 15, 1999, indicate that only five of nineteen members listed on the membership roster in effect at that time attended the meeting. The meeting lacked a quorum (two-thirds of its members as defined in the IRB procedures). The meeting also lacked a simple majority of members as required by 21 CFR 56.108(c). Further review of the minutes disclosed that review of an amendment to the [REDACTED] was approved by the IRB at that meeting. A significant protocol amendment to an investigational drug study [REDACTED] was reviewed and approved by the IRB during this meeting, also without a quorum present.
- Minutes of meeting of November 2, 1999, indicate that only seven of nineteen members listed on the membership roster in effect at that time attended the meeting. The meeting lacked a quorum (two-thirds of its members as defined in the IRB procedures). The meeting also lacked a simple majority of members as required by 21 CFR 56.108(c). Further review of the minutes disclosed that review of an amendment to the [REDACTED] was approved by the IRB at that meeting. IND Safety Reports for two investigational drug study studies [REDACTED] were reviewed by the IRB during this meeting, also without a quorum present.

The IRB failed to maintain minutes of the IRB's meetings in sufficient detail to show attendance at the meeting; actions taken by the IRB; the vote on these actions including the number of members voting for, against and abstaining as required by 21 CFR 56.115(a)(2).

Review of the minutes of the IRB meetings of June 8, 1999, September 15, 1999, and November 2, 1999, disclosed that the minutes do not clearly distinguish between "members present" and "member absent." Instead, the minutes list all members under the heading "Present" and then use "tick marks next to the listed member to denote their presence.

- Minutes of the IRB meeting of June 8, 1999, lacked a numerical vote for the initial review of the [REDACTED] This study was approved by the IRB at that meeting;
- Minutes of the IRB meeting of September 15, 1999, lacked a numerical vote for the review of a significant protocol amendment to an investigational drug study [REDACTED] which was reviewed and approved by the IRB during this meeting.

The IRB failed to maintain accurate listings of the IRB's membership. The IRB does not maintain listings of IRB members by names, earned degrees, or representative capacity as required by 21 CFR 56.115(a)(5).

For example, the list of IRB committee members, or roster, dated June 8, 1999, does not accurately reflect membership. This roster does not contain any identification of the non-scientific and non-affiliated members. In fact, the representative capacities for are missing or incomplete for 18 of the 19 members listed. One member, [REDACTED] is listed as "Community representation." The meeting minutes make no further clarification.

The violations listed above reflect a failure to meet fundamental requirements; you must inform this office, in writing, within fifteen (15) working days from the date of the receipt of this letter, of the actions you have taken or plan to take to bring the activities of the IRB into compliance with FDA regulations. Please include a copy of any revised documents, such as written procedures, with your response. Any submitted corrective action plan must include projected completion dates for each action to be accomplished. We will review your response and determine whether the actions are adequate to permit the IRB to continue unrestricted activities.


If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Failure to take prompt action to correct these violations and failure to respond may result in regulatory action without further notice, including disqualification of the IRB.

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Your response to this letter should be directed to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch II (HFZ-312), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Kathleen E. Swisher, R.N., J.D. A copy of this Warning Letter has been sent to the FDA's New Jersey District Office, 10 Waterview Drive, Parsippany, New Jersey 07054. We request that a copy of your response also be sent to the New Jersey District Office.

Please direct all questions concerning this matter to Ms. Swisher at (301) 594-4720, extension 138.

Sincerely yours,


for Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

cc: Michael Carome, M.D.
Office for Human Research Protections
Office of Public Health and Science
Office of the Secretary
6100 Executive Boulevard, Suite 3B01, MSC-7507
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L. Scott Larsen, M.D.
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